

Notice of Allowability

Application No.

09/173,821

Examiner

Sumesh Kaushal Ph.D.

Applicant(s)

RUDLAND ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 01/21/04.
2. ☒ The allowed claim(s) is/are 1,9,13,15-17 and 25-29.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 7.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


JEFFREY FREDMAN
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kimberly McGraw on 03/01/04.

The application has been amended as follows:

IN THE CLAIMS

Claims 1, 13, 17 and 25 has been amended as below:

Claim 1. (Currently amended) A neuronal cell line obtained from a transgenic rat which expresses a SV40tsA58 gene, the cells of which comprise:

- (i) a conditional oncogene, transforming gene or immortalizing gene or a cell cycle affecting gene operably linked to
- (ii) a cell type specific promoter,

in which the conditional oncogene, transforming gene or immortalizing gene or the cell cycle affecting gene is the SV40tsA58 gene, wherein the SV40tsA58 gene contains a thermolabile mutation of valine for alanine at position 438 in simian virus 40 T antigen gene

and in which the cell type specific promoter is a human NF-L gene promoter.

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Claim 13. (Currently amended) A method of producing a transgenic rat expressing a SV40tsA58 gene, comprising:

- (i) causing a female rat to super-ovulate by supplying her with a regular supply of Follicle Stimulating Hormone (FSH) prior to mating;
 - (ii) mating or artificially inseminating the female rat;
 - (iii) obtaining the resulting embryo from the female rat; and
 - (iv) incorporating
 - (i) a conditional oncogene, transforming gene or immortalizing gene or a cell cycle affecting gene operably linked to
 - (ii) a cell specific promoter into the genome of the rat embryo in which the conditional oncogene, transforming gene or immortalizing gene or the cell cycle affecting gene is said SV40tsA58 gene, wherein the SV40tsA58 gene contains a thermolabile mutation of valine for alanine at position 438 in simian virus 40 T antigen gene
- and in which the cell type specific promoter is a human NF-L gene promoter.

Claim 17. (Currently amended) A transgenic rat which expresses a SV40tsA58 gene whose germ cells and somatic cells contain

- (i) a conditional oncogene, transforming gene or immortalizing gene or a cell cycle affecting gene operably linked to
 - (ii) a cell type specific promoter as a result of chromosomal incorporation into the rat genome or into the genome of an ancestor of said rat
- in which the conditional oncogene, transforming gene or immortalizing gene or the cell cycle affecting gene is the SV40tsA58 gene, wherein the SV40tsA58 gene contains a thermolabile mutation of valine for alanine at position 438 in simian virus 40 T antigen gene
- and in which the cell type specific promoter is a human NF-L gene promoter.

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Claim 25. (Currently amended) A method of generating a cell line from a transgenic rat comprising a conditional oncogene, transforming gene or immortalizing gene or a cell cycle affecting gene operably linked to a cell specific promoter wherein the cell type specific promoter is a human NF-L gene promoter, the method comprising:

- (i) maintaining the rat at restrictive conditions such that the conditional oncogene, transforming gene or immortalizing gene or the cell cycle affecting gene is a SV40tsA58 gene, wherein the SV40tsA58 gene contains a thermolabile mutation of valine for alanine at position 438 in simian virus 40 T antigen gene and is expressed in vivo, only in a tissue of interest and in an inactive form such that the cells thereof grow normally;
- (ii) culturing said cells from the tissue of interest in vitro under permissive conditions such that the immortalizing function is activated, and
- (iii) subjecting the cells to non-permissive conditions so as to result in a cessation of growth and in differentiation.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Claims 1, 9, 13, 15-17, and 25-29 are free of prior art of record. The prior art does not teach or suggest a transgenic rat whose germ cells and somatic cells contain a transgene comprising SV40tsA58 oncogene (containing a thermolabile mutation of valine for alanine at position 438 in simian virus 40 T antigen gene) operatively linked to human NF-L gene promoter, wherein the cells obtained from the transgenic rat when culture under permissive conditions (33°C) results in immortalization of cells or elicits cessation of growth and differentiation under non-permissive conditions.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sumesh Kaushal,
Examiner Art Unit 1636


JEFFREY FREDMAN
PRIMARY EXAMINER
3/5/04